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## **REMARKS**

The Applicants have carefully studied the outstanding Office Action. The applicants have cancelled without prejudice, claims 105-107 currently on file, and are filing new claims 110-119. The present response is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are earnestly requested.

## **Specification**

The examiner has asserted that the title is not descriptive. The applicants have amended the title to "Portable Breath Collection System for use in Breath Tests" in order to attempt to comply with the examiner's request that the title be clearly indicative of the invention to which the claims are directed.

## **Claim objections**

The examiner has objected to claim 82 because of lack of antecedent basis for "said part". The applicants submit that the antecedent basis for "said part" is to be found in claim 78. However, to make the antecedent basis more accurate, the applicants have amended claim 82 to recite "said at least part".

The examiner has objected to claim 106 because the term "plateau volume of said breath" should be changed to "plateau value of the waveform of said breath". The applicants have canceled claim 106, thus rendering the examiner's objection moot. However, in new claim 111, the applicants have used the recitation "plateau value of the waveform of said breath", as suggested by the examiner.

## **Claim rejections - 35 USC § 112**

Claim 105 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The applicants have canceled claim 105, thus rendering the examiner's objection moot.

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However, in new claim 110, the applicants have recited the step of:

"analyzing said exhaled breath collected in said different sample containers for volatile organic compound content"

which the applicants believe makes it clear that the source of the VOC content detected is in the exhaled breath. Furthermore, the applicants now believe that the VOC absorbing trap does not now need to be recited in claim 110, as suggested by the Examiner, but can remain in dependent claim 112.

Claim 108 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for missing essential steps, such omission amounting to a gap between the steps.

The applicants have amended claim 108 essentially according to the examiner's suggestion, by adding the initial step of:

"measuring a first volume of said species over a unit of time"

and amending the last step to recite that:

"said second concentration measured is representative of the volume of said species over said unit of time in the subject's breath."

The applicants have not recited in the initial step that the first volume of said species over a unit of time is measured **by means of said breath test**, as suggested by the examiner, since in the present application, it is stated on page 24, lines 5-8 that " the exhaled volume of carbon dioxide is measured for a short period by using one of the known accurate measurement devices or methods, such as a calorimeter, or an integrated flow measurement method."

In view of the amendment made to claim 108, the applicants respectfully request withdrawal of the examiner's grounds for rejection of this claim under 35 U.S.C. 112, second paragraph.

#### **Claim rejections - 35 USC § 102**

Claims 66, 67, 69, 71-74, 76-79, 84, 86-89, 91, 95, 96, 98, 99, 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson, US 5,787,885 (hereinafter "Lemelson").

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Before responding to the examiner's rejections, the applicants wish to submit what they believe to be a number of basic differences between what is described in Lemelson, and the presently claimed invention.

The Lemelson patent, to the best of the present applicants' understanding thereof, describes "a device and method for sampling and testing the breath of human beings to detect maladies in the esophagus, stomach or gastrointestinal tract by the automatic analysis of the chemical contents of the sampled breath." (Emphasis added)

The various described embodiments of the Lemelson invention thus appear to be directed to an apparatus for the complete execution of collection and analysis of the exhaled breaths of the subject. Additionally, although the Lemelson invention does describe the use of multiple collection chambers for different samples, the direction of exhaled gas to those collection chambers is performed by one-way valves and pressure switches, as described in col. 4, line 43 to col. 5, line 11 of Lemelson. This is done in order to ensure collection of complete exhaled breaths and not of inhaled air, and to enable the subject to continue breathing normally. Nowhere, to the best of the applicants' understanding, does Lemelson show selection of complete exhaled breaths, or parts of exhaled breaths according to the characteristics of the breaths.

Furthermore, all of the breath analyses described in Lemelson are performed, to the best of the present applicants' understanding, on the already collected samples of breaths. Nowhere in Lemelson is there described or suggested the analysis of breaths as exhaled, in order to decide what samples of the exhaled breath to collect, or what parts of these samples of exhaled breath to collect.

Additionally, Lemelson appears, to the best of the present applicants' understanding, to describe a highly automated, microprocessor-controlled system, as illustrated in Fig. 4 thereof and associated description, which is intended to perform the breath collection and analysis functions without intervention of the subject.

Referring now to the details of the examiner's grounds for rejections with regard to claim 66, the applicants have amended claim 66 to recite:

"A system for collecting a plurality of samples of breath of a subject comprising:

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a breath conduit adapted to convey exhaled breath from the subject;  
**a sensor for determining a characteristic of said breath exhaled from the subject;**  
a plurality of sample containers for collection of said plurality of samples; and  
a sample distributor which directs different predetermined samples of said breath to different ones of said plurality of sample containers **according to the sensed characteristic of said exhaled breath.**" (Emphasis added)

Nowhere, to the best of the applicants' understanding, is there to be found or suggested in Lemelson, the emphasized aspects of the second and fourth elements of amended claim 66. Lemelson only shows sensing of a characteristic of the breath, in the form of analysis of the breaths, **after** the breaths have been collected in the collection chamber.

Support for this amendment, is to be found for example, at least in item 12 of Fig. 1, in claim 13 of the PCT application, and in part, in the incorporation of the limitation of claim 78 of the present application into claim 66.

The applicants therefore respectfully submit that amended claim 66 is free of the Examiner's grounds of rejection under 35 USC § 102(b) as being anticipated by Lemelson, that such rejection should be withdrawn, and amended claim 66 allowed.

Claims 67-94, as variously amended, are all dependent on amended claim 66, and recite additional patentable subject matter. Therefore, claims 67-94, as variously amended, are also deemed allowable.

Referring now to the details of the examiner's grounds for rejections with regard to claim 95, the applicants respectfully disagree with the Examiner's assertion that Lemelson shows "a valving system to select at least part of said breath, said valving system being actuated according to a physiological characteristic of the subject". The reference in Lemelson cited by the Examiner (col. 5, lines 39-42) refers to the rotary valve 30 of Figs. 2 and 3 of Lemelson, whose function is to direct the exhaled breath into one or other of the collection chambers 19A, 19B, 19C. The function of this rotary valve, if at all

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comparable to a recited element of claim 95 of the present application, is that of the "sample distributor" in the last element of claim 95, and not to the "valving system" of the second element of claim 95.

Nowhere, to the best of the applicants' understanding, is there to be found or suggested in Lemelson, a valving system which "selects at least part of said breath", i.e. a part of that breath which is conveyed from the subject through the breath conduit, and even if such a valving system were to be implied in Lemelson, a suggestion which the applicants strongly traverse, nowhere is there to be found in Lemelson, that that valving system for selecting at least part of the exhaled breath "is actuated according to a physiological characteristic of the subject".

The applicants therefore respectfully submit that (amended) claim 95 is free of the Examiner's grounds of rejection under 35 USC § 102(b) as being anticipated by Lemelson, that such rejection should be withdrawn, and (amended) claim 95 allowed.

Claims 96-104 are all dependent on (amended) claim 95, and recite additional patentable subject matter. Therefore, claims 96-104 are also deemed allowable.

Claims 108 and 109 are rejected under 35 U.S.C. 102(b) as being anticipated by Mault, US 5,179,958.

The Examiner has stated, *inter alia*, that Mault shows:

" .....monitoring a physiological parameter of the subject related to the metabolic rate of the subject, for change in said parameter between the measuring of said first concentration and said second concentration (col 4, lines 55-57); and

adjusting said second concentration according to change determined in said physiological parameter, such that said second concentration measured is representative of the volume of said species over said unit time in the subject's breath (col 4, lines 62-66)."

The applicants respectfully submit that nowhere in Mault is there shown or suggested that any change in a measured physiological parameter be used in order to

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adjust an exhaled breath component concentration, as recited in amended claim 108 of the present application.

According to Mault, the volumes are all measured directly, taking into account such variables as temperature and moisture content, while in this embodiment of the present invention, a volume measurement of the species is only performed from a single measurement, and the following volume measurements are determined from concentration measurements obtained from the breath test. The physiological parameter is only measured in order to maintain the accuracy of the measurement in case of change in the status of the subject.

The applicants therefore respectfully submit that amended claim 108 is free of the Examiner's grounds of rejection under 35 USC § 102(b) as being anticipated by Mault, that such rejection should be withdrawn, and amended claim 108 allowed.

Claim 109 is dependent on amended claim 108, and recites additional patentable subject matter. Therefore, claim 109 is also deemed allowable.

#### **Claim rejections - 35 USC § 103(a)**

Claims 105-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over various unspecified combinations of Lemelson, Hoberman (US 5,159,934) and Daniels (US 6,099,481).

The examiner has stated that:

"Lemelson teaches that said predetermined gas is a volatile organic compound. Although Lemelson does not explicitly state the phrase "volatile organic compound", the examiner notes that there is no limiting definition within the applicant's disclosure as to the limitations of the phrase. Thus, the examiner is taking the broadest reasonable definition of the phrase, in light of the disclosure, wherein "volatile organic compound" may mean any substance detectable from human expired breath that have high enough vapor pressure to vaporize into a gaseous form. Since Lemelson teaches that his teachings can be used to

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automatically analyzing the chemical contents within the breath of living beings for analysis of a variety of conditions and diseases of said living being, the examiner regards Lemelson to teach the limitations of the claim."

The applicants respectfully disagree with this broad interpretation. The term "volatile organic compound" (VOC) is widely known, both in the art and in general knowledge, as defining a group of chemicals whose effects have serious repercussions both on the environment, and on the health to those exposed thereto. There is even an official definition of what constitutes a VOC by the United States Environmental Protection Agency, as published in the Code of Federal Regulations. There is also a vast body of literature which refers to these aspects of VOC's, including numerous publications and patent documents, whose aim is the detection of such VOC's. The importance of the subject is such that there is even considerable legislation in many countries regarding the allowability levels of VOC emission and contamination.

Therefore, the examiner's dismissal of the term VOC as having "no limiting definition within the applicant's disclosure as to the limitations of the phrase", and therefore capable of a broad interpretation, is strongly traversed by the applicants.

The applicants also believe that nowhere did Lemelson, Hoberman or Daniels mention or even consider the special requirements of the detection of VOC's, as described in the present claimed application.

Furthermore, it is clear from the Examiner's comments regarding claim 93 that his citation of Lemelson, Hoberman and Daniels is unrelated to the aspect regarding VOC's recited in original claim 107 of the present application. The Examiner states that:

"Lemelson recognizes the importance of cleaning out the chambers, utilizing a water trap and flushing mechanism to clean out the chambers (Fig. 2, 29). In addition, the expulsion of gas from a container by means of using the properties of thermal expansion is a well known technique in the field. It is the examiner's position that it would not be beyond the ability of one of ordinary skill in the art to modify Lemelson with a heated chamber in order to remove residual sample gas molecules which may adversely affect future usage of the container as an alternative to the existing liquid/water trap."

However, in the present application, the claimed use of an absorbing "trap", which is

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what the Examiner has correctly understood (in paragraph 7 of his Office Action) as the "material which absorbs at least part of said breath of said subject" as recited in original claim 107, is not intended to be "in order to remove residual sample gas molecules which may adversely affect future usage of the container as an alternative to the existing liquid/water trap". Such use is a cleaning use.

In contrast to such a use, in the present claimed invention, the "absorbing trap" is one embodiment for **collecting** the VOC content of the exhaled breath, not for **eliminating** it, and is thus totally unrelated to a cleaning process. In other words, the object of the "absorbing trap" and its optional heating process is to positively collect and store a component of the exhaled breath for ultimate analysis, and not to eliminate undesirable contaminants, which would appear to be the meaning which the Examiner has understood.

Claims 105-107 have been cancelled, without prejudice, by the applicants, such that the Examiner's rejection thereof is moot. However, claims 105-107 have been replaced by new method claims 110-112, such that the applicants' above-mentioned arguments and comments are considered to be equally applicable to new claims 110-112. The applicants therefore earnestly request that any corresponding rejections under 35 U.S.C. 103(a) not be applied to new claims 110-112, and that these claims be allowed.

#### **New claims**

New claims 113-116 recite a manually actuated apparatus, as shown in Fig. 2C of the present application, and associated description. The Examiner has stated, in connection with his grounds of rejection of claims 68 and 100 that "Lemelson does not teach a sample distributor which is operated manually. However, Lemelson does disclose an automatic sample distributor, and it would not be beyond the ability of one of ordinary skill in the art to utilize a manually operated sample distributor when the end result is equivalent."

The applicants respectfully submit that Lemelson actually teaches away from the use of a manually actuated device, since, as previously stated, Lemelson describes a highly automated, microprocessor-controlled system, which performs breath collection and analysis functions without intervention of the subject. The applicants regard the presently claimed invention involving a simple manually operated apparatus as novel and inventive over

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Lemelson, as it provides a collection only apparatus without the expense and complexity described in Lemelson.

Claims 117-119 are method claims which describe a method of analyzing multiple samples of exhaled breath by collection of the breath within the recited plurality of collection containers, such that these containers can be analyzed at a remote site, thereby utilizing the simplicity and portability of the claimed invention, as shown in Figs. 7A and 7B of the application, ands associated description.

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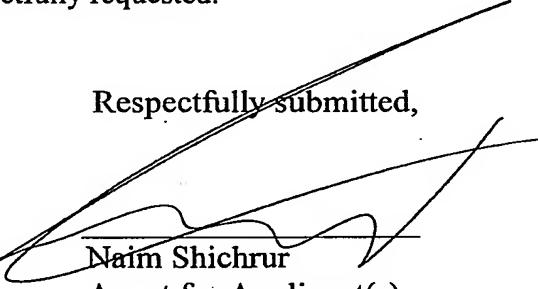
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### Conclusion

The applicants therefore respectfully submit that all of the claims 66-104 and 108-109, as variously amended, are novel and unobvious over the prior art cited by the Examiner, and are therefore deemed to be allowable. Additionally, the applicants respectfully submit that all of new claims 110-119 are novel and unobvious over the prior art cited by the Examiner, and are also deemed to be allowable. Reconsideration and prompt allowance of this application are therefore respectfully requested.

Respectfully submitted,

  
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